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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,862	07/12/1999	PHILIP E. THORPE	4001.002282	1339

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/29/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/351,862

Applicant(s)

THORPE ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 28 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 April 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,3-12,14,19-29,34,35 and 39-42.

Claim(s) withdrawn from consideration: 2,13,16-18,30 and 36-38.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Continuation of 2. NOTE: The newly added claims 44-48 and the amended claim 12 change the scope of the rejected claimed invention. Accordingly, further search or consideration is required.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants improperly attempt to narrow the scope of the claim by reading limitations of the specification into a claim or implicitly adding limitations which have no express basis in the claim. see *In re Morris*, 44 USPQ2d 1023, 1027-28 (Fed.Cir. 1997). With respect to rejection of claims 1, 3-12, 14, 19-22, 39-43 under 35 USC 102 (e) over *Schroit* US Patent 6,300,308, Examiner states that Applicant's reliance on *Lockheed Martin Corp v. Space Systems/Loral Inc.* 58 USPQ2d 1671 and *In re Cortright*, 49 USPQ2d 1464 is misplaced because the factual scenarios in each of the cited case laws are not applicable in this case. *Lockheed Martin* reasoning is based on improper broadening of a "means plus function" claim which is controlled by 35 USC 112 para 6. The instant claims do not fall under such statutory interpretation of claims. Other cited case laws like *In re Cortright*, are directed to such claim construction where the prior art applied during the prosecution presented a teaching away from the meaning of the claim as defined in their respective specifications. This is not the case here, because the scope of the claims do not exclude the teachings of the cited references and the cited references do not provide teachings away from the scope of the pending claims. Contrary to Applicant's contention, no where does the instant specification interpret the limitation "a second anti-cancer agent other than the first anti-aminophospholipid antibody or fragments thereof" to exclude such combinations as taught in *Schroit*. Applicant essentially argues that the claims at issue are not directed to an "anti-aminophospholipid antibody conjugate," but to a naked or unconjugated anti-aminophospholipid antibody or fragment thereof in combination with a second, distinct anti-cancer agent. However, the pending claims do not recite such limitations as argued, namely the naked or unconjugated antibody, thus, the argument is moot because they argue unclaimed limitations.

Moreover, such limitations are not exclusive of the combinations taught by *Schroit* because the definitions provided in the instant specification falls within the teachings of *Schroit*. The instant Specification at pages 32 and 19 sets forth the scope of the limitations "at least first anticancer agents with at least a first antibody....." and at least a second anti-cancer agent other than said at least a first antibody." At page 32, the specification defines the first limitation described above to be inclusive of naked anti-aminophospholipids, but not limiting to such moieties. Further, the first at least anticancer agent may be considered to be at least a second anti-cancer agent. (see lines 1-32). Therefore, reading the meaning of such limitations in view of the specification indicates that two separate doses of the first anticancer agent meets the limitations of the instant claims, because the second cancer agent can be the same as the first cancer agent. Furthermore, at page 19 of the instant specification, anti-aminophospholipids are defined to be used "co-extensively with naked or unconjugated anti-aminophospholipids. Subsequently, the term 'naked' was described to be in no way exclusive of combinations of antibody with other therapeutic agents" (see page 19 of the instant spec at lines 10-17). Therefore, antibody-therapeutic conjugates of *Schroit* is within the scope of the instant limitations, because *Schroit* teaches anti-PS antibody compositions in a kit form that can be administered separately (see col 7-8) and at least each antibody composition of *Schroit* contains an antibody directed to PS and a polypeptide such as diphtheria toxoid. Applicant also argues that *Schroit*'s two compositions are the same anticancer agents. The instant claims do not exclude such compositions because as defined in page 19 and 32 of the instant specification the first and second anticancer agent are the same. Applicant also states that claim 21 of *Schroit* are not concerned with naked antibodies. In response, Examiner states pending claims are not limited to such limitations. Assuming arguendo that they were, the specification defines the term "naked antibodies" to include antibody-therapeutic agent conjugates of *Schroit* (see specification at page 19, line 15-17). Applicant's arguments with respect to the rejection of claims under 35 USC 103(a) over *Schroit*, *Gimbrone* and *Umeda* have been fully considered but are not persuasive for the reasons of record and further as reasoned above. Finally, the information set forth in Exhibit A was considered but were not found persuasive because they are directed to antibodies that are not claimed here.

Improper Finality-

Applicant's arguments directed to a premature finality of the third Office Action have been fully considered but are not persuasive, because the finality is proper under legal procedures set forth in MPEP 706.07(a). Under MPEP 706.07 (a) subsequent actions on merits shall be final except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment, or is based on IDS submitted under 37.CFR .97(c), or contains new rejections.

Neither of the scenarios above applies here because claims 3-12, 14, 19-22 and 39-42 were effectively rejected under 35 USC 103(a) in the previous Office Action. In fact, neither any new grounds of rejection or reasoning thereof was presented on the Final Office Action, nor any new prior art was applied or added to the grounds of rejection already on the record. Contrary to Applicant's Arguments, the enumeration of claims 3-12, 14, 19-22 and 39-42 on the heading of the rejection, in the Final Action, was not a new grounds of rejection because the Office Action filed on Dec, 12, 2002, Paper No. 20 rejected claims 23-29 and 34-35 which all depend on claims 3-12, 14, 19-22. Claims 3-12, 14, 19-22 were also rejected under 102 (e) over *Schroit*. Therefore, once the dependent claims were rejected under obviousness analysis, their base claims are also effectively rejected, because absence such rational the dependent claims can never be rejected under obviousness analysis. Accordingly, contrary to Applicant's assertions, this rejection does not constitute a new ground of rejection; because lack of novelty is the epitome of obviousness. *In re May*, 574 F.2d. 1082, 197 USPQ 601, 607 (CCPA 1978). Here, no new grounds of rejection were presented. Claims were rejected over the same issues and same cited prior art. Therefore, Applicants were on proper notice that claims 3-12, 14, 19-22 were also rejected under 103 (a) obviousness analysis. Thus, the finality of last Office Action was proper and hereby maintained.

Applicantion SN 09/351,149-

Applicants arguments with respect to the provisional double patenting rejection that exists in Sn 09/351,149 have been noted but are not relevant here, because prosecution of SN 09/351,149 ('149) is separate from the instant application. Applicants further appear to argue that the pending application should contain a double patenting rejection over the co-pending application 09/351,149. In response, Examiner states that the purpose of a provisional double patenting rejection is to place Applicant on proper notice about the overlapping nature of the claimed subject matter. It appears that Applicant has properly been served of such notice to maintain the co-pending claims patentably separate. Nevertheless, to the extent it is relevant, Examiner points out that the claims in '149 application are generic to the the instant pending claims. The generic claim of '149 may not necessarily render the instant species claims obvious. Accordingly, a one-way obviousness double patenting rejection is made in '149 to put Applicant on notice of their burden. Nonetheless, at anytime the claims of the pending application would contain obvious subject matter over the copending application '149, a double patenting rejection may be applied.